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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,872	12/07/2000	Jean-Baptiste Dumas Milne Edwards	78.US3.REG	9916

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 10/22/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/731,872

Applicant(s)

MILNE EDWARDS ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,9-12,24,25,28,29 and 37-43 is/are pending in the application.
- 4a) Of the above claim(s) 1,9-12,24,25,28,29,42 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1, 9-12, 24, 25, 28, 29 and 37-43 are pending.

Applicants' amendment filed on August 14, 2002 (Paper No. 10) is acknowledged.

Claims 30-36 have been cancelled, and new claims 37-43 have been added.

### ***Election/Restrictions***

2. Applicant's election with traverse of Group V, claims 37-41, drawn to polypeptide, and SEQ ID NO:253 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that newly added claims 42 and 43 are drawn to methods of making polypeptides of claims 37-41, and in view of the Patent Office Group Practice of combining a method of making an elected polypeptides with the polypeptide, when the claim is not limited to polypeptides encoded by non-elected polynucleotides. This is not found persuasive because newly submitted claims 42 and 43 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 42 and 43 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Therefore, claims 37-41 and SEQ ID NO:253 are examined.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 37-41 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The claims are directed to a purified polypeptide comprising an amino acid sequence of a mature or full-length polypeptide of SEQ ID NO:253 (claims 37-40) and a purified polypeptide comprising a full-length or mature amino acid sequence encoded by a human cDNA of Clone 105-095-2-0-G11-CS in ATCC accession number PTA-1218 (claim 41). The polypeptide of SEQ ID NO:253 along with SEQ ID NO:243 are disclosed as members of glycerophosphodiester phosphodiesterase (GP-PDE) protein family, interact with RGS 16 (Regulator of G protein Signaling) protein, and as such, play important roles in both lipid metabolism and in G protein signaling (page 347, lines 1-3). The specification (page 346), discloses that the 331-amino-acid protein of SEQ ID NO:243 is highly homologous to the putative glycerophosphodiester phosphodiesterase MIR-16 (membrane Interacting protein of RGS16) protein (GenBank accession no. AAF65234), and the protein is a likely variant of the MIR16 protein, and a BLAST search with the amino acid sequence of SEQ ID NO:243 further indicates the protein is homologous to GP-PDEs of *E. coli* and *Haemophilus influenzae* (page 346, line 3-12). The specification also indicates MIR 16 protein, which is homologous to the protein SEQ ID NO:243 was identified in a yeast two hybrid screen of pituitary cell cDNA library using the RGS 16 protein as a bait (Zheng et al., Proc. Natl. Acad. Sci. 97, 3999-4004 (2000); page 346, lines 20-23), and from sequence alignments of MIR16 with other GP-PDEs (Fig. 2 in Zheng et al. (2000)), the N-terminal region of MIR16 (amino acids 70-150), immediately after the putative signal peptide, is highly conserved (40-61% similarity), suggesting that it may contain residues

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critical for catalytic activity, i.e., the catalytic site. The putative enzymatic activity of MIR16 and its interaction with RGS16 suggest that it may play important roles in lipid metabolism and G protein signaling (Page 346, lines 27-33). However, the sequence alignments of SEQ ID NO:253 (108 amino acids) with MIR16 (331 amino acids) and SEQ ID NO:243 (331 amino acids) indicate that SEQ ID NO:253 has 79.3% sequence identity with MIR16 or SEQ ID NO:243 (see attached sequence comparison), and the amino acids 1-87 of SEQ ID NO:253 are matched with MIR16 or SEQ ID NO:243 except for positions 44 and 45, but, the amino acids 88-108 of SEQ ID NO:253 (LRMEQQAWSWTLSSLLTGFLS) are not matched with those of MIR16 or SEQ ID NO:243 (AAKNGATGVELDIETSDGIP). From the sequence comparison of SEQ ID NO:253 to MIR16, it appears SEQ ID NO:253 only contains a portion (residues 70-87) of the putative catalytic site (residues 70-150), thus it is not known whether SEQ ID NO:253 is a functional protein without indicating its GP-PDE activity. Since SEQ ID NO:253 as being a functional GP-PDE has not been demonstrated in the specification, thus, its functional role is not established. For these reasons, the instant invention does not possess a specific or a well-established utility, although there is a general utility that is applicable to the broad class of GP-PDE. The utility is not a substantial utility because it requires further research to identify or reasonably confirm a "real world" context of use. Basic research to characterize the claimed invention, use in an assay to identify modulators of the instant invention, or production of antibodies to identify other related proteins do not constitute substantial utilities.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 37-41 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 38-40 are indefinite because the claim is dependent from a cancelled claim.

***Conclusion***

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.  
Patent Examiner

*CMK*

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October 15, 2002

*Karen Cochrane Carlson Ph.D.*  
KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER